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| APPLICATION NO.       | F        | ILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|-----------------------|----------|--------------|----------------------|-------------------------|------------------|--|
| 10/088,561 03/19/2002 |          | 03/19/2002   | Jerry M Collins      | 31978-178825            | 6698             |  |
| 26694                 | 7590     | 03/06/2003   |                      |                         |                  |  |
| VENABLE               | E, BAETJ | ER, HOWARD A | EXAMINER             |                         |                  |  |
| P.O. BOX 3<br>WASHING |          | 20043-9998   |                      | JONES, DAMERON          |                  |  |
|                       |          |              |                      | ART UNIT                | PAPER NUMBER     |  |
|                       |          |              | 1616                 |                         |                  |  |
|                       |          |              |                      | DATE MAILED: 03/06/2003 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| •   |   | Application N .          | Applicant(s)  |                |  |  |  |  |  |
|---|---|--------------------------|---|----------------|--|--|--|--|--|
|   |   | 10/088,561               | COLLINS ET AI   | COLLINS ET AL. |  |  |  |  |  |
|   | Office Action Summary   | Examiner                 | Art Unit  |                |  |  |  |  |  |
|   |   | D. L. Jones              | 1616  |                |  |  |  |  |  |
| The MAILING DATE of this communication appears n the cover sheet with the correspondence address  |   |                          |   |                |  |  |  |  |  |
| Period for Reply  |   |                          |   |                |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status |   |                          |   |                |  |  |  |  |  |
| 1)  | Responsive to communication(s) filed on   |                          |   |                |  |  |  |  |  |
| 2a)□  | ·   | —<br>is action is non-fi | nal.  |                |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |   |                          |   |                |  |  |  |  |  |
| <u> </u>  | on of Claims  |                          |   |                |  |  |  |  |  |
| •   | Claim(s) <u>1-40</u> is/are pending in the application  |                          |   |                |  |  |  |  |  |
|   | 4a) Of the above claim(s) is/are withdrav   | vn from consider         | ation.  |                |  |  |  |  |  |
| · ·   | Claim(s) is/are allowed.  |                          |   |                |  |  |  |  |  |
| · _   | Claim(s) is/are rejected.   |                          |   |                |  |  |  |  |  |
| · <u> </u>  | Claim(s) is/are objected to.  |                          |   |                |  |  |  |  |  |
| •   | Claim(s) <u>1-40</u> are subject to restriction and/or e on Papers  | election requirem        | ent.  |                |  |  |  |  |  |
|   | The specification is objected to by the Examiner  | r                        |   |                |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |   |                          |   |                |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |                          |   |                |  |  |  |  |  |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.  |   |                          |   |                |  |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |   |                          |   |                |  |  |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |   |                          |   |                |  |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |   |                          |   |                |  |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |   |                          |   |                |  |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |   |                          |   |                |  |  |  |  |  |
|   | 1. Certified copies of the priority documents have been received.   |                          |   |                |  |  |  |  |  |
|   | 2. Certified copies of the priority documents have been received in Application No  |                          |   |                |  |  |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |                          |   |                |  |  |  |  |  |
| . 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |   |                          |   |                |  |  |  |  |  |
| a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  |   |                          |   |                |  |  |  |  |  |
| Attachment(s)   |   |                          |   |                |  |  |  |  |  |
| 2) 🔲 Notic  | e of References Cited (PTO-892)<br>e of Draftsperson's Patent Drawing Review (PTO-948)<br>nation Disclosure Statement(s) (PTO-1449) Paper No(s) |                          | Interview Summary (PTO-413) Paper I<br>Notice of Informal Patent Application (I<br>Other: |                |  |  |  |  |  |

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## **RESTRICTION INTO GROUPS**

1. Restriction is required under 35 USC 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous antitumor labeled drugs (e.g., paclitaxel, docetaxel, doxorubicin, epirubicin, mitoxantrone, topotecan, and other drugs useful in the treatment of solid tumors), the following groups of inventions are set forth.

Group I, claim(s) 1-29 and 31, drawn to an antitumor labeled drug, methods of making, and use thereof wherein the labeled drug is 11C-paclitaxel.

Group II, claim(s) 1-27 and 30, drawn to an antitumor labeled drug, methods of making, and use thereof wherein the labeled drug is 11C-docetaxel.

Group III, claim(s) 1-18 and 32-38, drawn to an antitumor labeled drug, methods of making, and use thereof wherein the labeled drug is 11C-doxorubicin.

Group IV, claim(s) 1-18, 32-34, and 37, drawn to an antitumor labeled drug, methods of making, and use thereof wherein the labeled drug is 11C-epirubicin.

Group V, claim(s) 1-18, drawn to an antitumor labeled drug and use thereof wherein the labeled drug is 11C-mitoxantrone.

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Group VI, claim(s) 1-18, 39, and 40, drawn to an antitumor labeled drug, methods of making, and use thereof wherein the labeled drug is 11C-topotecan.

Group VII, claim(s) 1, 2, 4-6, 8-11, and 13-18, drawn to an antitumor labeled drug and use thereof wherein the labeled drug is one <u>not encompassed</u> by Groups I-VI above.

**Note**: Claims appearing in more than one Group will only be examined to the extent that they read on the elected invention.

2. In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. It should be noted that the groups above are not exhausted since Group VII above is directed to ANY antitumor labeled drugs and use thereof that is not one of the drugs disclosed in Groups I-VI. In particular, it would be impossible for the Examiner to list all possible drugs that would encompass Group VII due to time constraints and the sheer volume of drugs that could be labeled. Therefore, Applicant may choose to elect a single invention encompassed in Group VII by identifying another specific embodiment supported by the specification that is not listed in Groups I-VI above and the Examiner will generate a Group directed to that antitumor labeled drug.

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3. Applicant is entitled to a product, a process specifically adapted for that product, and a use of that product. Thus, the Groups as set forth encompass a product, use of that product, and/or a method of making the product.

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- 4. Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 because they lack the same or corresponding special technical features since each group comprises products that neither anticipate nor render obvious another product, use of the product, and a method of making the product.
- 5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).
- 6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640.

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The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Primary/Examiner
Art Unit 1616

March 5, 2003